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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/089,105	02/19/1998	David B Kay	ORTHO-A-CIP-PCT.US	4870
7590	08/15/2005		EXAMINER	
Hudak & Shunk 2020 FRONT STREET, SUITE 307 CUYAHOGA FALLS, OH 44221-3256			WOO, JULIAN W	
			ART UNIT	PAPER NUMBER
			3731	

DATE MAILED: 08/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No. 10/089,105	Applicant(s) KAY, DAVID B	
	Examiner Julian W. Woo	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 4/8/05.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 22-27, 29, 54 and 55 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 22-27, 29, 54 and 55 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

2. Claims 22-27, 29, 54, and 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over DeCaro (4,762,453) in view of Limpert (2,033,039), and further in view of Rosenman (5,728,116). DeCaro discloses the invention substantially as claimed. DeCaro discloses, in the figures and in col. 2, line 66 to col. 3, line 38, a tissue anchor and a method of making the anchor, where the anchor comprises a rigid elongate member (10) having an open helical structure, a first end having an insertion tip (31), and a second end having a modular attachment head (12); where the elongate member normally comprises a spring steel, where the modular head includes a hexagonal recess (16), where the elongate member includes a seat (3) that is ring that

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is less than a complete circle (i.e., a partial helix gripping the modular head) and a complete circle (i.e., a complete helix also gripping the modular head), where the ring has the same outer diameter as the open helical structure, and where the modular head includes an opening (19, in fig. 9). However, DeCaro does not disclose as claimed the dimensions of the open, helical structure. Nevertheless, DeCaro discloses that the structure can be made in "a number of configurations" (see col. 1, lines 58 and 59). Thus, it would have been a matter of design choice to dimension the structure as claimed. The dimensions can be chosen according to the intended use of the anchor. Moreover, it would have been obvious to one having ordinary skill in the art at the time the invention was made to dimension the structure as claimed, since it has been held that discovering optimum values of result effective variables involve only routine skill in the art. Also, DeCaro does not disclose that the spring steel material of the helical structure is surgical grade or stainless, and that the tissue anchor can be made of titanium or a bioabsorbable material. DeCaro does not disclose a modular attachment head that is substantially the same size or smaller than the outer diameter of the helical structure, and that the modular attachment head has an opening. Limpert teaches a modular attachment head that is substantially the same size or smaller than the outer diameter of the helical structure, and that the modular attachment head has an opening. It would have been obvious to one having ordinary skill in the art at the time the invention was made, in view of Limpert, to modify the head of DeCaro, so that the modular head is substantially the same size or smaller than the outer diameter of the helical structure, and that the modular attachment head has an opening. Such

modifications would allow the anchor of DeCaro to be driven with a rotating tool, such that the torque and insertion force are directed over the helical structure without affecting the surrounding tissue or structure around the anchor. Additionally, Rosenman teaches, in col. 5, line 41 to col. 6, line 54, small tissue anchors with helical structures and heads, which can be made of stainless steel, titanium, or a bioabsorbable material or equivalent materials. Thus, it would have been obvious to one having ordinary skill in the art at the time the invention was made, to manufacture the anchor of DeCaro in view of Limpert out of stainless steel, titanium, or a bioabsorbable material; since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of design choice. That is, it would have been obvious to one having ordinary skill in the art at the time the invention was made, to apply surgical grade or stainless steel or titanium to the anchor of DeCaro. Such metals not only possesses mechanical strength and springiness, they are corrosion-resistant and hence, biocompatible. Also, it would be a matter of design choice to apply a bioabsorbable material, if a surgeon desires such a material for therapeutic purposes.

Response to Amendment

3. Applicant's arguments with respect to claims 22-27, 29, 54, and 55 have been considered but are moot in view of the new ground(s) of rejection.

In response to Applicant's argument that the Examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon

hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper.

Conclusion

4. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Julian W. Woo whose telephone number is (571) 272-4707. The examiner can normally be reached Mon.-Fri., 7:00 AM to 3:00 PM Eastern Time, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anh Tuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Julian W. Woo
Primary Examiner

August 10, 2005